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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/513,024	02/25/00	VILEN	B 2879-64

HM12/0831

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EXAMINER	
ROARK, J	
ART UNIT	**PAPER NUMBER**
1644	6

DATE MAILED: 08/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/513,024	Vilen et al.
Examiner	**Group Art Unit**
Jessica Roark	1644

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-49* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-49* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Sequence compliance

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is reminded that the rules apply to sequences of four or more amino acids, such as the sequence found on page 37, line 11 of the specification as-filed.

restriction requirement

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
I. Claims 1-33, drawn to a method to desensitize a receptor with a regulatory compound, classified in Class 424, subclass 137.1; and class 514, subclass 2.
II. Claims 34-43, drawn to an isolated regulatory compound that desensitizes a receptor, classified in Class 424, subclass 137.1; and class 514, subclass 2.
III. Claim 44-46, drawn to a method for identifying compounds useful for desensitizing a receptor by causing dissociation of the receptor, classified in Class 436, subclass 63, 86.
IV. Claim 47,48, drawn to a method for identifying compounds useful for desensitizing a receptor by inhibiting association of receptor components, classified in Class 436, subclass 63, 86.
V. Claim 49, drawn to a method of sensitizing a receptor, classified in Class 424, subclass 137.1; and class 514, subclass 2.

3. Groups I, III, IV, V are unique methods. They differ with respect to ingredients, method steps, and endpoints. Therefore, they are patentably distinct.

4. Groups II and I are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group II can be used for affinity purification.

5. Groups (II and III) and (II and IV), respectively, are related as products and method of identifying said products. However, the method steps do not define the structure of the claimed products. Therefore, they are patentably distinct

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of any or these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

Species Election

7. This application contains claims directed to the following patentably distinct species of the claimed Inventions:

i) Inventions I/II/III/IV/V : wherein the receptor is A) a B cell antigen receptor, B) a pro-B cell receptor, C) a pre-B cell receptor, D) and Ig FC receptor, and E) a natural killer receptor

These species are distinct because their structures and modes of action are different. The examination of species (A)-(E) would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 34, 44, 47, and 49 are generic.

ii) Inventions I/II/III/IV : wherein the receptor desensitization is due to A) dissociation of the components and B) inhibition of component association.

These species are distinct because their modes of action differ, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 34, 44, 47, and 49 are generic.

iii) Inventions I/II : wherein the regulatory compound is A) an antibody, B) an mimetope, C) a peptide, and D) a peptide mimetope.

These species are distinct because their structures and modes of action are different. The examination of species (A)-(D) would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 34 are generic.

iv) Inventions I/II : wherein the antibody A) is specific for the transducer component and B) is bi-specific.

These species are distinct because their structures and modes of action differ, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 34 are generic.

v) Inventions I/II : wherein the transducer component is A) Igα and B) Igβ.

These species are distinct because their structures and modes of action are different. Therefore, they represent patentably distinct subject matter

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 34 are generic.

vi) Inventions I : wherein the B cell receptor is expressed by A) an autoreactive B cell, B) a B cell comprising a B cell receptor that selectively binds to antigens on a graft, C) a B cell lymphoma, and D) a chronic lymphocytic leukemia cell.

These species are distinct because the B cell receptors are involved in different pathological conditions, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

vii) Inventions I: wherein the autoimmune disease is A) RA, B) SLE, C) IDDM, D) MS, E) myasthenia gravis, F) Grave's disease, G) AIHA, H) ITP, I) Goodpasteur's syndrome, J) pemphigus vulgaris, K) acute rheumatic fever, L) post-streptococcal glomerulonephritis, and M) polyarteritis nodosa.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

viii) Inventions I : wherein the Ig FC receptor is A) FcαRI, B) FcεRI, C) FcγRI, D) FcγRIIa, E) FcγRIIb, F) FcγRIIc, and G) FcγRIIIb.

These species are distinct because their structures and modes of action are different. The examination of species (A)-(E) would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

ix) Inventions I : wherein the cell type is a A) mast cell and B) a basophil.

These species are distinct because these cell types are involved in different pathological conditions, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

x) Inventions I : wherein the thereapeutic composition is administered A) *in vivo*, and B) *ex vivo*.

These species are distinct because the method steps differ, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 am to 4:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, PhD.
Patent Examiner
Technology Center 1600
August 16, 2000

PHILLIP GAMBEL
PRIMARY PHILLIP GAMBEL
PATENT EXAMINER
GROUP 1600
TECH CENTER 1600
8/30/00

Application No.: 09/513,024

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE